

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

DMB

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[Docket No. 2003N-0142]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

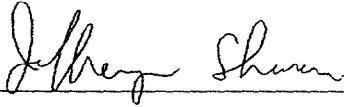
**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 23, 2003 (68 FR 43532), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0445. The approval expires on November 30, 2006.

A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: 12-9-03

December 9, 2003.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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